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10/533,361	10/21/2005	Kerry Burton	44-05	2350

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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,361	BURTON ET AL.	
	Examiner	Art Unit	
	Catherine S. Hibbert	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,8-10 and 12-17* is/are pending in the application.

4a) Of the above claim(s) *8,9,16 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,10 and 12-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 April 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/31/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is the First Office Action on the Merits of US Application No. 10/533,361, filed 4/29/2005, which claims priority to PCT/GB2003/004716, filed October 31, 2003, which claims priority to GB application 0225390.4, filed October 31, 2002. Claims 5, 7 and 11 are cancelled. Claims 8-9, 16-17 are withdrawn. Claims 1-4, 6, 8-10 and 12-17 are pending. Claims 1-4, 6, 10 and 12-15 are under examination in this action.

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-15) and of the species Claim 6 (from among claims 5-11) in the reply filed on 3 January 2008 is acknowledged. Examiner notes that the species election requirement regarding claims 14 and 15 has been withdrawn. The traversal is on the ground(s) that Applicants disagree with the characterization of the Van Griensven et al reference stated in the Restriction Requirement that Van Griensven et al anticipates the special technical feature (the filamentous fungus transcription promoter of claim 1) and that it would not be a burdensome search to search both Groups I and II together.

This is not found persuasive for reasons already of record and because Van Griensven et al, in "Hydrophobins from Edible Fungi, Genes, Nucleotide Sequences, And DNA-Fragments Encoding for Said Hydrophobins, and Expression Thereof" (WO 96/41882, published 27 December 1996, made of record in the IPER) teach an *A. bisporus* filamentous fungus transformed with a heterologous DNA under the control of a filamentous fungus promoter which is substantially active during regulation of the

fruiting bodies thereof (see whole document and especially abstract and 102(b) rejection below) which reads on the promoter of Claim 1. Therefore, the special technical feature is anticipated by Van Griensven et al and is therefore not novel. Restriction is proper because the invention of Group I is distinct from the invention of Group II because the filamentous fungus of Group I can be used in a materially different method than the method of Group II, such as for growth cycle and media studies. Therefore, the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph. In addition, the inventions have acquired a separate status in the art due to their recognized divergent subject matter; the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries) and the prior art applicable to one invention would not likely be applicable to another invention.

The requirement is still deemed proper and is therefore made FINAL.

Claims 8-9 and 16-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3 January 2008.

Drawings

The drawings are objected to because Figure 1 is missing the label "Fig.1" and Figure 5 has an illegible label for "Fig.5". Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (page 14, paragraph 2). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The disclosure is also objected to because it contains a typographical error in the duplication of the word "the" (page 1, paragraph 3, line 4); in the word "windrow" (page 1, paragraph 4, line 4), and in the phrase "in the by the" (page 8, paragraph 5, line 5).

The use of the trademarks ABI Prism™ has been noted in this application (e.g. page 14, paragraph 2, line 7). It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, 6, 10 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 3 are indefinite in reciting, respectively, "wherein the promoter is active only from veil-break onwards during the development of the fruiting body of the fungus" and "wherein the promoter is active only during stages 4-7 of the development of the fruiting body of the fungus". Both of the terms "only from veil-break onwards" and "only during stages 4-7" represent embodiments that are explicitly excluded from Claim

1 which states that “the promoter is substantially up-regulated during the development of the fruiting body, between the button stage, late than stage 1, and the veil-break stage". Therefore Claims 2 and 3 do not have an antecedent basis in Claim 1.

Claims 6 and 10 are indefinite because it is unclear whether the term "or a sequence which hybridizes thereto" is referring to the sequence shown in SEQ ID NO:12 and 35, respectively, (representing 60% sequence identity to SEQ ID NO:12 and 35) or whether the term "or a sequence which hybridizes thereto" is referring to the mutants and variants of SEQ ID NO:12 and 35, (representing 60% sequence identity to mutants or variants of SEQ ID NO:12 and 35 and therefore representing less than 60% sequence identity to SEQ ID NO:12 and 35). Therefore, one of ordinary skill in the art would not be able to determine the metes and bounds of Applicants invention.

Regarding Claim 15, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a

required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, for example, claim 15 recites the broad recitation “pesticidal compounds, and the claim also recites BT toxin which is the narrower statement of the range/limitation. Claim 15 recites “such as...” in several phrases throughout the claim. It is unclear how the recitation of the various exemplary compounds following the phrase “such as” is intended to limit the claim scope. For instance, it is unclear how the recitation lectins and pesticidal compounds such as Bt toxin as examples is intended to constrain the scope of the encoded “secondary metabolites”. For example, is the recitation of Bt toxin intended to limit the secondary metabolites that are pesticidal compounds to having some property in common with Bt toxin (e.g., effective against mosquitoes)? In addition, it is unclear whether the recitation “antibodies, including other diagnostic material” is meant to limit the DNA encoding antibodies only to those that include other diagnostic material or whether the recitation is meant to indicate that the antibodies might but are not required to include other diagnostic material.

Additionally, Claim 15 is indefinite in the use of the term "and" in line 6, because the term “and” infers that the heterologous DNA encodes the entire combination of components listed. In light of the instant specification which states "although not limited thereto, it is generally preferred to limit the number of heterologous expression products to one, two or three (page 10, paragraph 7), it is unclear whether the claim requires the

heterologous DNA to encode *all* of the components together and one of ordinary skill in the art would not be able to determine the metes and bounds of Applicants invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6, 10 and 12-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus …") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not a sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include:

a. Actual reduction to practice,

b. Disclosure of drawings or structural chemical formulas,

c. Sufficient relevant identifying characteristics,

i. Complete structure

ii. Partial structure

iii. Physical and/or chemical properties

iv. Functional characteristics when coupled with a known or disclosed correlation between function and structure,

d. Method of making the claimed invention,

e. Level of skill and knowledge in the art, and

f. Predictability in the art.

Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

In the instant case, Claims 1-3 are directed to promoters delimited as having specific function but unlimited structure. Unless the structure of a broad genus of promoters having the required function or the structural determinants of the recited

function are already known in the art or disclosed in the application one would not recognize that applicant was in possession of the generic promoter of the claims.

In addition, Claims 6 and 10 are drawn to a filamentous fungus transformed with a heterologous sequence of DNA, the fungus being capable of expressing the heterologous DNA, characterized in that the heterologous DNA is under the control of a filamentous fungus transcription promoter which is substantially active later than stage 1 of the development of the fruiting body of the fungus and which is substantially up-regulated during development of the fruiting body, between the button stage, later than stage 1, and the veil-break stage and further limited to wherein the DNA is operably linked with a promoter comprising the sequence of SEQ ID NO. 12 and a terminator comprising the sequence of SEQ ID NO 35, or a mutation or variant of either, or a sequence which hybridizes thereto under conditions of at least 60% sequence identity.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim(s) 1-4, 6, 10 and 12-15 are broad and generic, with respect to all possible compounds encompassed by the claims. Although the structure of the essential element of SEQ ID NO:12 and SEQ ID NO:35 are provided in the specification, and one of skill in the art would be able to determine mutants and variants of SEQ ID NO:12 and SEQ ID NO:35 using computer program analysis and would be able to determine sequences that hybridize to SEQ ID NO:12 and SEQ ID NO:35 under conditions of at least 60% sequence identity, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds

beyond those compounds specifically disclosed in the examples in the specification, and therefore, one of ordinary skill in the art would not be able to determine which of the species of variants of SEQ ID NO:12 and 35 would retain the promoter/termination function as described in Claim 1. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus. While having written description of SEQ ID NO:12 and SEQ ID NO:35, and compounds identified in the specification tables and/or examples, the specification does not provide sufficient descriptive support for the myriad of compounds embraced by the claims.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4 and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Griensven et al, in "Hydrophobins from Edible Fungi, Genes, Nucleotide Sequences, And DNA-Fragments Encoding for Said Hydrophobins, and Expression Thereof" (WO 96/41882, published 27 December 1996, of record).

Claims 1/4 are drawn to a filamentous fungus/*A. bisporus* transformed with a heterologous sequence of DNA, the fungus being capable of expressing the heterologous DNA, characterized in that the heterologous DNA is under the control of a filamentous fungus transcription promoter which is substantially active later than stage 1 of the development of the fruiting body of the fungus and which is substantially up-regulated during development of the fruiting body, between the button stage, later than stage 1, and the veil-break stage.

Claims 12-14 further limit the fungus according to claim 1, to wherein a selectable marker is linked with the heterologous DNA (Claim 12), to wherein the heterologous DNA is native DNA (Claim 13), and to wherein the heterologous DNA is selected such as to affect characteristics of mushroom crop production (Claim 14).

Van Griensven et al teach *A. bisporus* filamentous fungus transformed with a heterologous DNA under the control of a filamentous fungus promoter which is active during regulation of the fruiting bodies (see whole document and especially abstract). For example, Van Griensven et al teach "the *hyp A* and *hyp B* genes are, for instance, fruit body specific and show different expression levels during the various stages of *Agaricus bisporus* fruit body development. The *hyp B* gene shows highest expression

during the early stages of fruit body development whereas the *hyp A* gene shows high mRNA expression levels from the onset of fruiting at least until the growth stage in which the fruit bodies are used for consumption." In addition, Van Griensven et al state that "the invention is however not restricted to a certain mechanism of action or structural purpose of the hydrophobins of the invention within the fungus or fruit body," and continue "it is to be understood that the invention not only provides for the hydrophobins as they naturally occur in edible fungi, but also to proteins and peptides that 'essentially correspond' to the hydrophobins of the invention" (e.g. page 7, lines 8-22).

Therefore, Van Griensven et al meets all the limitations of the instant Claims 1, 4 and 12-14.

Allowable Subject Matter

SEQ ID NO:12 and SEQ ID NO: 35 appear to be free of the prior art.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Hibbert, Ph.D., whose telephone number is (571)270-3053. The examiner can normally be reached on M-F 8AM-5PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D., can be reached on 571-272-0739. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Respectfully submitted,

Catherine S. Hibbert
Examiner/AU1636

/Daniel M Sullivan/
Primary Examiner, Art Unit 1636